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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,562	12/12/2003	Ken Michlitsch	USGINZ02512	2406
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LEVINE BAGADE HAN LLP 2400 GENG ROAD, SUITE 120 PALO ALTO, CA 94303			EXAMINER DORNBUSCH, DIANNE	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/734,562	Applicant(s) MICHLITSCH ET AL.	
	Examiner DIANNE DORNBUSCH	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 22, 2009 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 21-25, 36, 37, and 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sonnenschein et al. (2001/0056282) in view of El Gazayerli (6,159,146) and further in view of Sauer et al. (6,997,931).

Sonnenschein discloses the following claimed limitations:

Claim 21: A method for performing a medical procedure within a hollow body organ of tortuous or unpredictably supported anatomy ([0001] and [0080]), the method comprising: advancing an overtube (48) within the hollow body organ in a flexible state ([0081] and Fig. 6A position a); transitioning the overtube to a rigid state to thereby substantially fix the shape of the overtube in any desired configuration ([0083]-[0084])

and Fig. 6A position a'); advancing a plication device (61, 61A) through the overtube (the plication device is advance through the overtube in the manufacturing process since when the overtube is placed into the stomach it already contains the plication device); and forming a tissue fold within the hollow body organ with the plication device (Fig. 6B, 7, 10, and 11).

Claim 22: The method further comprising visualizing formation of the tissue fold ([0219]).

Claim 23: The method wherein visualizing formation of the tissue fold further comprises visualizing formation with a visualization element advanced through the overtube ([0022], [0043], and [0063] where the visualization means goes from the distal end to the proximal end of the overtube through image channel (113) seen in Fig. 17).

Claim 24: The method wherein visualizing formation of the tissue fold further comprises visualizing formation with a visualization element coupled to the overtube ([0022], [0043], and [0063] where the components of the visualization means have to be coupled to the distal end and the proximal end of eh overtube in the channel (113)). Endoscopes contain a lens at the end of the image channel (113) which is coupled to the end so there is no fluid going into the rest of the device as well as to avoid unwanted motion of the lens.

Claim 25: The method wherein the medical procedure comprises endoscopically treating gastroesophageal reflux disease ([0062]), advancing the overtube within a hollow body organ comprises advancing the overtube through a patient's esophagus and into the patient's stomach (Fig. 6 and 10), transitioning the overtube to a rigid state

comprises transitioning the overtube to a rigid state in a configuration enabling access to the patient's gastroesophageal junction ([0083]-[0084] and Fig. 6A position a'), and forming a tissue fold comprises forming at least one tissue fold in a vicinity of the patient's gastroesophageal junction ([0044] and Fig. 6B, 7, 10, and 11) ([0080]-[0086]).

Claims 36 and 40: The method wherein the medical procedure comprises endoscopically treating a bleeding site within a patient's gastrointestinal tract ([0062]), advancing the overtube within a hollow body organ comprises advancing the overtube through the patient's esophagus or colon (Fig. 6 and 10), transitioning the overtube to a rigid state comprises transitioning the overtube to a rigid state in a configuration enabling access to the bleeding site ([0083]-[0084] and Fig. 6B and 11 where the location is where a bleed is occurring or where the tumor is located), and forming a tissue fold comprises forming at least one tissue fold with a plication device advanced through, or coupled to, the overtube, so that the bleeding site is disposed on the tissue fold ([0044] and Fig. 6B, 7, 10, and 11).

Claim 37: The method further comprising removing the lesion or cancer. It is inherent that if a tumor or lesion is found in the body it will be removed.

Claim 41: The method further comprising securing the tissue fold, thereby reducing bleeding from the bleeding site (the tissue fold is secured with the staples as seen in Fig. 9B).

Claim 42: The method wherein securing the tissue fold further comprises securing the tissue fold with an anchor assembly (the staples are an anchor assembly as seen in Fig. 9B).

Sonnenschein teaches all the claimed limitations discussed above however, Sonnenschein does not disclose that the overtube comprises a plurality of nested elements having mating contoured surfaces and that the rigid state is caused by imposing a load that clamps the contoured surfaces of adjacent nested elements together.

El Gazayerli discloses a method for performing a medical procedure within a hollow body organ of tortuous or unpredictably supported anatomy (Fig. 1), the method comprising: advancing an overtube (16 which is made by components 28) comprising a plurality of nested elements (28) having mating contoured surfaces (30, 32 as seen in Fig. 4C) within the hollow body organ in a flexible state (Fig. 1); transitioning the overtube to a rigid state by imposing a load that clamps the contoured surfaces of adjacent nested elements together to thereby substantially fix the shape of the overtube in any desired configuration (Col. 4 Lines 24-32).

The overtube of El Gazayerli is configured by a plurality of linkages/nested elements (28) which are connected to each other by core (34) and wires (44) which are used to move the device into predetermined shapes (Fig. 2) by causing a load (tensioning) on the nested elements which makes the contoured surfaces clamp against each other and it locks in place in order to maintain the position to place the staples (Fig. 2 and Col. 5 Lines 28-42).

Sonnenschein discloses the claimed invention except that for the overtube being made of a flexible tube instead of a plurality of nestable elements (links). El Gazayerli shows that an overtube with links or with flexible tubing is an equivalent structure known

in the art. Therefore, because these two movable joints were art-recognized equivalents at the time the invention was made, one of ordinary skill in the art would have found it obvious to substitute the flexible tube for a plurality of nestable elements/links.

Furthermore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Sonnenschein with an overtube made of nestable elements in view of the teachings of El Gazayerli, in order to provide the device with the exact orientation of each contoured surfaces on the nestable elements which will ensure proper functioning of the nestable elements so the fundus is properly aligned with the staples.

Sonnenschein in view of El Gazayerli teaches all the claimed limitations discussed above however, Sonnenschein in view of El Gazayerli does not disclose that the plication device is advance through the overtube after the overtube has been transitioned to the rigid state.

Sauer discloses a method for performing a medical procedure within a hollow body organ of tortuous or unpredictably supported anatomy (Fig. 29A), the method comprising: advancing an overtube (combination of 12 and 14); transitioning the overtube to a rigid state (the overtube is the combination of an accessory tube (12) and an endoscope (14) where the endoscope is a well known gastroscope which includes a locking mechanism for the distal movement of the endoscope in the handle which would make the movable portion to be rigid and locked in position (the locking/moving knob is seen in the handle of the endoscope in Fig. 1 which is a well known mechanism in the

endoscopes). By locking the endoscope in place it will also lock the accessory tube) to thereby substantially fix the shape of the overtube in any desired configuration (Fig. 1).

Sauer also discloses a plication device 16 which can be inserted through the accessory tube (12), the working channel of the endoscope (14), or by itself (Col. 22 Lines 29-37). When inserted into the overtube (12 and 14) it is done after the overtube has been inserted into the patient as seen in Fig. 29.

Note that Sauer does not specify that the overtube is locked in a rigid position prior to inserting the plication device. However, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to lock the endoscope in the desired position prior to insertion of the plication device since the examiner is taking Official Notice that the locking of the endoscope into a desired location for the procedure is well known in the art in order to prevent undesired movement of the endoscope and plication device while the procedure is being performed. Furthermore, it is well known in the art to first lock the endoscope into position prior to inserting other instrumentation such as the plication device in order to ensure the position of the procedure and clean the area if necessary by using the suction and irrigation of the endoscope.

The device of Sonnenschein is a single device that is inserted into the body of the patient instead of two separate components where one is inserted prior to the other one. Sauer shows a plication device which can be inserted as a single device into the body or through an overtube such as the accessory tube (12) or the working channel of an endoscope (14). Therefore, because the insertion means were art-recognized

equivalents at the time the invention was made, one of ordinary skill in the art would have found it obvious to use an endoscope working channel or the combination of the accessory tube and endoscope disclosed by Sauer instead of inserting the single device.

Furthermore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Sonnenschein in view of El Gazayerli with an overtube that transitioned to the rigid state prior to insertion of the plication device in view of the teachings of Sauer and the Official Notice above, in order to ensure the position of the procedure and clean the area if necessary by using the suction and irrigation of the endoscope.

4. Claims 26-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sonnenschein et al. (2001/0056282) in view of El Gazayerli (6,159,146) and Sauer et al. (6,997,931) and further in view of Kalloo et al (2002/0022851).

Claims 26:

Sonnenschein discloses the method wherein the medical procedure comprises endoscopically performing gastric reduction ([0062]), advancing the overtube within a hollow body organ comprises advancing an overtube through a patient's esophagus and into the patient's stomach (Fig. 6 and 10), transitioning the overtube to a rigid state comprises transitioning the overtube to a rigid state in a desired configuration within the patient's stomach ([0083]-[0084] and Fig. 6A position a'), and forming a tissue fold ([0044] and Fig. 6B, 7, 10, and 11).

Sonnenschein discloses the claimed invention except for a plurality of tissue folds in the patient's stomach. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make more than one fold in the stomach, since it would be necessary for the particular procedure to have several folds in order to reduce the size of the stomach.

Additionally, Kalloo shows as plurality of folds performed in a gastric reduction procedure (Fig. 11).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Sonnenschein in view of El Gazayerli and Sauer with more than one fold in a gastric reduction procedure in view of the teachings of Kalloo, in order to securely fold more than one location to reduce the total size of the stomach.

Claims 27-30 and 32-35:

Sonnenschein in view of El Gazayerli and Sauer teaches all the claimed limitations discusses above, however Sonnenschein in view of El Gazayerli and Sauer does not disclose the steps of partitioning the stomach with a plurality of tissue folds nor the end structure of the stomach.

Kalloo discloses the following claimed limitations:

Claim 27: The method further comprising approximating and securing the plurality of tissue folds ([0033]), thereby partitioning the patient's stomach into at least first (the pouch at the base disclosed in paragraph [0033]) and second chambers (the collapsed/closed off portion of the stomach disclosed in paragraph [0033]) over at least a portion of the stomach.

Claim 28: That forming, approximating and securing a plurality of tissue folds further comprises: forming, approximating and securing a first plurality of tissue folds in a first plane (the first plane is one side of the periphery of the stomach seen in Fig 7); and forming, approximating and securing at least one additional plurality of tissue folds in at least one additional plane (the second plane is the opposing side of the first plane in Fig. 7 where the rope is attached to the wall of the stomach in both sides in order to enclose a portion of the stomach by bringing the two planes together), wherein the first plane and the at least one additional plane are substantially parallel to one another.

Claim 29: That partitioning the stomach into first and second chambers further comprises partitioning the stomach into a first lumen (the first chamber disclosed as the pouch at the base of the esophagus has a lumen for receiving the food and digesting it ([0033])) and a second chamber (the collapsed/closed off portion of the stomach disclosed in paragraph [0033]).

Claim 30: That partitioning the stomach into a first lumen and a second chamber further comprises partitioning the stomach such that the patient's gastroesophageal junction only communicates with the first lumen ([0033] where the pouch is at the base of the esophagus in order to receive the food and digest it).

Claim 32: That forming a plurality of tissue folds further comprises forming a plurality of tissue folds inferior to the patient's gastroesophageal junction (Fig. 7 where the clip is being placed below the esophagus junction).

Claim 33: That forming a plurality of tissue folds further comprises forming a plurality of tissue folds having at least one tissue fold from an anterior segment of the

patient's stomach (the anterior segment is one side of the periphery of the stomach seen in Fig 7) and at least one tissue fold from an opposing posterior segment of the patient's stomach (the posterior segment is the opposing side of the anterior segment in Fig. 7 where the rope is attached to the wall of the stomach in both sides in order to enclose a portion of the stomach by bringing the two segments together).

Claim 34: That forming a plurality of tissue folds within a patient's stomach comprises forming and securing a plurality of tissue folds disposed at substantially randomly selected locations to reduce a volume of the stomach (Fig. 11 where there are multiple folds which are randomly placed depending at the location of the rope).

Claim 35: That forming a plurality of tissue folds within a patient's stomach comprises forming a plurality of interconnected tissue folds (Fig. 11) around a perimeter of the patient's stomach (the folds are made around a perimeter where the rope is located which is a loop in the stomach that is later closed to separate the stomach into two chambers) with instruments advanced through, or coupled to, the overtube (Fig. 7-11), the method further comprising approximating the plurality of interconnected tissue folds to remodel the stomach to an hourglass profile ([0033]).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Sonnenschein in view of El Gazayerli and Sauer with the steps of partitioning the stomach with a plurality of tissue folds and having a specific end structure of the stomach which contains two chambers in view of the teachings of Kalloo, in order to be able to securely close the stomach into two separate chambers where one acts as a smaller stomach that helps the patient loose weight.

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Claim 31:

Sonnenschein in view of El Gazayerli, Sauer, and Kalloo discloses the claimed invention except for the first lumen having a volume in the range of 10-50 cm³. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a volume in the range of 10-50 cm³ on the first lumen, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

5. Claims 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sonnenschein et al. (2001/0056282) in view of El Gazayerli (6,159,146) and Sauer et al. (6,997,931) and further in view of Reed (2003/0165887).

Sonnenschein in view of El Gazayerli and Sauer teaches all the claimed limitations discussed above, however Sonnenschein in view of El Gazayerli and Sauer does not disclose removing the lesion or cancer with cutting apparatus such as a snare.

Reed discloses removing the lesion or cancer with cutting apparatus such as a snare [0111].

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Sonnenschein in view of El Gazayerli and Sauer with removing the lesion or cancer with a cutting apparatus such as a snare in view of the teachings of Reed, since the use of cutting tools such as snares are well known biopsy techniques that can be used through the port of endoscopes like the one used by Sonnenschein.

6. Claims 43-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sonnenschein et al. (2001/0056282) in view of El Gazayerli (6,159,146).

Sonnenschein discloses the following claimed limitations:

Claim 43: A method for performing a medical procedure within a hollow body organ of tortuous or unpredictably supported anatomy ([0001] and [0080]), the method comprising: advancing a main body (48) within the hollow body organ in a flexible state ([0081] and Fig. 6A position a), the main body having a plication device (61, 61A) coupled to a distal region thereof (Fig. 5 and [0163]); and the plication device comprising a tissue grabbing assembly (63 and the combination of 62 and 62a where part 63 brings the fundus into contact with the lower esophagus which forms the fold as disclosed in [0168] and Fig. 6-7) and a flexible tube (69) containing one or more tissue anchors (70 where the flexible tube contains the anchors and the plication device 61, 61a until the components (62, 62a and 61, 61a) are aligned [0180])); transitioning the main body to a rigid state to thereby substantially fix the shape of the overtube in any desired configuration ([0083]-[0084] and Fig. 6A position a'); and forming a tissue fold within the hollow body organ with the plication device (Fig. 6B, 7, 10, and 11).

Claim 44: The method further comprising visualizing formation of the tissue fold ([0219]).

Claim 45: The method wherein visualizing formation of the tissue fold further comprises visualizing formation with a visualization element advanced through the overtube ([0022], [0043], and [0063] where the visualization means goes from the distal end to the proximal end of the overtube through image channel (113) seen in Fig. 17).

Claim 46: The method wherein visualizing formation of the tissue fold further comprises visualizing formation with a visualization element coupled to the overtube ([0022], [0043], and [0063] where the components of the visualization means have to be coupled to the distal end and the proximal end of eh overtube in the channel (113)). Endoscopes contain a lens at the end of the image channel (113) which is coupled to the end so there is no fluid going into the rest of the device as well as to avoid unwanted motion of the lens.

Claim 47: The method wherein the medical procedure comprises endoscopically treating gastroesophageal reflux disease ([0062]), advancing the overtube within a hollow body organ comprises advancing the overtube through a patient's esophagus and into the patient's stomach (Fig. 6 and 10), transitioning the overtube to a rigid state comprises transitioning the overtube to a rigid state in a configuration enabling access to the patient's gastroesophageal junction ([0083]-[0084] and Fig. 6A position a'), and forming a tissue fold comprises forming at least one tissue fold in a vicinity of the patient's gastroesophageal junction ([0044] and Fig. 6B, 7, 10, and 11) ([0080]-[0086]).

Sonnenschein teaches all the claimed limitations discussed above however, Sonnenschein does not disclose that the overtube comprises a plurality of nested elements having mating contoured surfaces and that the rigid state is caused by imposing a load that clamps the contoured surfaces of adjacent nested elements together.

El Gazayerli discloses a method for performing a medical procedure within a hollow body organ of tortuous or unpredictably supported anatomy (Fig. 1), the method

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comprising: advancing an overtube (16 which is made by components 28) comprising a plurality of nested elements (28) having mating contoured surfaces (30, 32 as seen in Fig. 4C) within the hollow body organ in a flexible state (Fig. 1); transitioning the overtube to a rigid state by imposing a load that clamps the contoured surfaces of adjacent nested elements together to thereby substantially fix the shape of the overtube in any desired configuration (Col. 4 Lines 24-32).

The overtube of El Gazayerli is configured by a plurality of linkages/nested elements (28) which are connected to each other by core (34) and wires (44) which are used to move the device into predetermined shapes (Fig. 2) by causing a load (tensioning) on the nested elements which makes the contoured surfaces clamp against each other and it locks in place in order to maintain the position to place the staples (Fig. 2 and Col. 5 Lines 28-42).

Sonnenschein discloses the claimed invention except that for the overtube being made of a flexible tube instead of a plurality of nestable elements (links). El Gazayerli shows that an overtube with links or with flexible tubing is an equivalent structure known in the art. Therefore, because these two movable joints were art-recognized equivalents at the time the invention was made, one of ordinary skill in the art would have found it obvious to substitute the flexible tube for a plurality of nestable elements/links.

Furthermore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Sonnenschein with an overtube made of nestable elements in view of the teachings of El Gazayerli, in order to provide the

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device with the exact orientation of each contoured surfaces on the nestable elements which will ensure proper functioning of the nestable elements so the fundus is properly aligned with the staples.

7. Claims 48 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sonnenschein et al. (2001/0056282) in view of El Gazayerli (6,159,146) and further in view of Kalloo et al (2002/0022851).

Claim 48:

Sonnenschein discloses the method wherein the medical procedure comprises endoscopically performing gastric reduction ([0062]), advancing the overtube within a hollow body organ comprises advancing an overtube through a patient's esophagus and into the patient's stomach (Fig. 6 and 10), transitioning the overtube to a rigid state comprises transitioning the overtube to a rigid state in a desired configuration within the patient's stomach ([0083]-[0084] and Fig. 6A position a'), and forming a tissue fold ([0044] and Fig. 6B, 7, 10, and 11).

Sonnenschein discloses the claimed invention except for a plurality of tissue folds in the patient's stomach. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make more than one fold in the stomach, since it would be necessary for the particular procedure to have several folds in order to reduce the size of the stomach.

Additionally, Kalloo shows as plurality of folds performed in a gastric reduction procedure (Fig. 11).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Sonnenschein in view of El Gazayerli with more than one fold in a gastric reduction procedure in view of the teachings of Kalloo, in order to securely fold more than one location to reduce the total size of the stomach.

Claim 49:

Sonnenschein in view of El Gazayerli teaches all the claimed limitations discusses above, however Sonnenschein in view of El Gazayerli does not disclose the steps of partitioning the stomach with a plurality of tissue folds nor the end structure of the stomach.

Kaloo discloses that forming, approximating and securing a plurality of tissue folds further comprises: forming, approximating and securing a first plurality of tissue folds in a first plane (the first plane is one side of the periphery of the stomach seen in Fig 7); and forming, approximating and securing at least one additional plurality of tissue folds in at least one additional plane (the second plane is the opposing side of the first plane in Fig. 7 where the rope is attached to the wall of the stomach in both sides in order to enclose a portion of the stomach by bringing the two planes together), wherein the first plane and the at least one additional plane are substantially parallel to one another.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Sonnenschein in view of El Gazayerli with the steps of partitioning the stomach with a plurality of tissue folds and having a specific end structure of the stomach which contains two chambers in view of the teachings of

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Kaloo, in order to be able to securely close the stomach into two separate chambers where one acts as a smaller stomach that helps the patient loose weight.

Response to Arguments

8. Applicant's arguments with respect to claims 21-42 have been considered but are moot in view of the new ground(s) of rejection.

9. Applicant's arguments filed September 22, 2009 with respect to claims 43-49 have been fully considered but they are not persuasive.

Applicant argues that Sonnenschein does not include a tissue grabbing assembly and a flexible tube containing one or more tissue anchors. The examiner disagrees, as explained in the rejection above, Sonnenschein does disclose these limitations (see rejection above where the limitations are explained).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANNE DORNBUSCH whose telephone number is (571)270-3515. The examiner can normally be reached on Monday through Thursday 7:30 am to 5:00 pm Eastern.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. D./

Examiner, Art Unit 3773

/(Jackie) Tan-Uyen T. Ho/

Supervisory Patent Examiner, Art Unit 3773